



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

June 21, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-59

Frank Dulcich, President  
Pacific Seafood Group  
3220 S.W. First Avenue  
Portland, Oregon 97201

**WARNING LETTER**

Dear Mr. Dulcich:

We inspected your firm, Washington Crab Producers, Inc. located at 1980 North Nyhus, Westport, Washington, on April 16-17, 2001, and again on May 10-11, 2001. As part of those inspections, in-line sub samples of cooked and peeled shrimp meat as well as swabs from various locations within the manufacturing plant were collected and analyzed for Listeria monocytogenes (L. Mono). The analysis revealed the product to be positive for L. mono. As a result, the product is adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the bacterium L. Mono may have rendered the food injurious to health. On or about May 9, 15, and 31, 2001, June 4, and 8, 2001, you were sent reports of sample analysis signed by Carlos Abeyta and/or Cheryl Eklund, Acting Director(s) of Microbiology, informing you of these results.

In addition, a sample was collected from [REDACTED] which consisted of frozen cooked and peeled shrimp from Lot # 010501, produced by Washington Crab Producers, Inc. Westport, Washington. This sample was also analyzed and found positive for L. Mono contamination. As a result, this product is also adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the bacterium L. Mono may have rendered the food injurious to health.

During the April 16-17, 2001, inspection, we found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to Glen A. White, General Manager at the conclusion of the inspection. These deviations cause your refrigerated, cooked and peeled shrimp meat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

Frank Dulcich, President  
Pacific Seafood Group  
Portland, Oregon  
Re: Warning Letter SEA 01-59  
Page 2

The deviations were as follows:

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedures or frequency of checking the temperature and belt speed at the cooking critical control point to control pathogen survival listed in your HACCP plan for cooked, peeled shrimp, air packed, refrigerated, or frozen. Your HACCP plan calls for monitoring the temperature and belt speed once every [REDACTED] Your records fail to show the time of the observation.

During the inspection the investigator also noted that the calibration of the belt speed and cooker thermometers had not been documented and that calibration of belt speed and cooker thermometers were not listed as verification steps in your HACCP plan. If either the temperature or the belt speed is out of specification it could contribute to the findings of L. Mono in your finished product or on your processing equipment.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Frank Dulcich, President  
Pacific Seafood Group  
Portland, Oregon  
Re: Warning Letter SEA 01-59  
Page 3

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

*for* *Charles M. Breen*  
Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: WSDA with disclosure statement